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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,316	05/24/2001	Zongxuan Jin	100967-00011	1362

7590 05/21/2003

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/863,316

Applicant(s)

JIN ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 5-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachm nt(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Response to Amendment

Objection of claims 5 and 9 is no longer maintained in view of the amendment.

Rejection of claims 5, 7-9 and 11-12 under 35 U.S.C. § 102(a) is no longer maintained in view of the amendment.

Response to Arguments

The rejection made in paper number 10 over Yamada et al. under 35 U.S.C. §103(a) is maintained and is hereby repeated. Applicant's arguments filed February 20, 2003 have been fully considered but they are not persuasive. Applicant asserts that even though Yamada teaches that sericin can be used to counter the ill effects of lipid peroxides, which effects can include cancer, there are myriad types of cancer with very different preventative treatments for each. The examiner is in agreement with these assertions and since skin cancer is a type of cancer, an antioxidant, such as sericin is recognized to be effective in inhibiting many types of cancer, including skin cancer.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition of skin cancer in a mouse with a shaved back by chemically inducing cancer with 7, 12-dimethylbenzen[α]anthracene (DMBA)

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and 12-o-tetradecanoyl-phorbol13-acetate (TPA), it does not reasonably provide enablement for inhibiting skin cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claim 10 is drawn to a method of inhibiting **skin cancer** in a mammal with an effective amount of sericin. The nature of the invention is extremely complex in that it encompasses the actual inhibition of skin cancer such that the subject treated with sericin does not contract skin cancer.

Breadth of the Claims: The complex of nature of the claim is greatly exacerbated by breadth of the claim. The claims encompass inhibition of skin cancer in mammals which have potentially many different causes such as heredity (familial history of skin cancer, fair skin individuals, European heritage), environment such as UV exposure, multiple nevi or atypical moles, exposure to coal and arsenic compounds, elevation (UV light is stronger as elevation increases because thinner atmosphere at higher altitude cannot filter UV as effectively as it does at sea level), latitude (the rays of the sun are strongest near the equator), repeated

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exposure to x-rays, and scars from disease and burns. Each of these defects may or may not be addressed by the administration sericin to inhibit skin cancer.

Guidance of the Specification: The guidance given by the specification as to how one would administer sericin to a mammal in order to actually inhibit skin cancer is minimal. All of the guidance provided by the specification is directed towards a working example of mice with shaved backs, wherein the cancer initiator DMBA is applied, and the cancer promoter TPA is applied to the skin on their backs to induce a cancer. One group was treated with topical sericin in addition to the cancer promoting agents.

Working Examples: All of the working examples provided by the specification are directed toward the inhibition of a cancer caused by DMBA and TPA.

State of the Art: While the state of the art is relatively high with regard to inhibition of skin cancer for specific causes such as UV exposure, the state of the art with regard to inhibition of skin cancer broadly is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to inhibit skin cancer caused by exposure to x-rays.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual inhibition of skin cancer caused by UV exposure or heredity or exposure to x-rays or skin that has scars or burns or chemicals other than DMBA and TPA makes practicing the claimed invention unpredictable in terms of inhibition of skin cancer in general.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a cause of the skin cancer, then a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system and test the combination in the model system to determine whether or not the combination is effective for inhibition of skin cancer. If unsuccessful, which is likely, given the lack of significant guidance from the specification or prior art with regard to inhibition of skin cancer with sericin, one of skill in the art would have to then either envision a modification of the composition dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance from the specification of prior art regarding inhibition of skin cancer in general, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to inhibit the development of skin cancer in a mammal by administration of sericin.

Therefore, a method of inhibiting skin cancer by administering sericin is not considered to be enabled by the instant specification.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

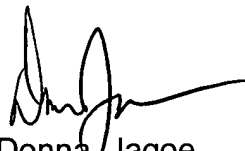
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Donna Jagoe
Patent Examiner
Art Unit 1614

dj
May 15, 2003



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SUPERVISORY PATENT EXAMINER
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